Remarks

Applicants thank the Examiner and her Supervisor for the helpful interview on February 5, 2009. The amendments discussed and suggested by the Examiner and her supervisor have been incorporated in the claims to place them in condition for allowance.

Amendments to the Claims

As discussed during the interview, a number of limitations have been added to the claims to more specifically define a device that is able to deliver a small, precise amount of a pharmaceutical formulation directly to a patient's upper vaginal vault for transvaginal drug delivery.

Enclosed is an illustration of the female pelvic region. As shown in this illustration the upper vaginal vault is located at the top of the vaginal canal, adjacent to the cervix.

The device defined by the claims is inserted into the vagina until the flange at the distal end touches the patient's body and prevents further insertion of the device. The pharmaceutical formulation is delivered through the opening at the proximal end directly to the patient's upper vaginal vault.

Independent claims 1 and 6 have been amended to delete references to rectal applicators. Further, the independent claims, as amended, specify that applicator barrel has a size and shape suitable for insertion into the vagina, preventing penetration of the vaginal wall or cervix, and delivering a pharmaceutical composition to the upper vaginal vault. Support for this amendment can be found in the specification at least at page 2, lines 8-11.

Amended claims 1 and 6 also clarify that the medication chamber has a diameter that is smaller than the inner diameter of the applicator barrel and defines a cavity having a volume of 1 mL or less. The amended claims also clarify the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel. Support for these amendments can be found in the specification at least at Figures 2B and 2D and page 3, line 27 until page 4, line 2 and original claim 1.

Claims 1 and 6 have been rearranged to indicate that the plunger tip is at the proximal end of the plunger.

Additionally, claims 1 and 6 have been amended to specify that the applicator contains a flange at the distal end of the applicator. Support can be found in dependent claim 2, as originally filed, and at page 3, line 26. Dependent claim 2 has been canceled in view of this amendment.

Additionally, dependent claims 8 and 10 have been canceled and incorporated into independent claim 6.

Support for new claims 12 and 13 can be found in the specification at least at page 3, lines 25-27.

Applicants respectfully request entry of the amendment since it further narrows the claims, does not raise any new issues, and places the claims in condition for allowance.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1 and 6 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection.

Legal Standard

The general standard for the written description requirement is that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See* M.P.E.P. § 2163(I). An applicant may show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

With respect to original claims, the M.P.E.P. states that "there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." M.P.E.P. § 2163(I) (A), *citing In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).

Analysis

The Examiner objected to the term "up to 1 mL" and indicated that page 4 of the Specification used different phrasing. Applicants respectfully point out that the term "1 mL or

less" was used in claim 1 as originally filed. However, as suggested by the Examiner and her Supervisor, Applicants have amended claims 1 and 6 and pages 2, 4, and 5 to use the phrase used in original claim 1, *i.e.* "1 mL or less". Therefore claims 1 and 6 meet the written description requirement.

Rejection Under 35 U.S.C. § 102/103

Claims 1, 3-6, and 8-11 were rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 2,847,011 to Jones ("Jones"). Claim 2 was rejected under 35 U.S.C. § 103(a) as being obvious over Jones. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 2 was canceled and incorporated into independent claims 1 and 6. Claims 8 and 10 have been canceled and incorporated into independent claim 6. Therefore the comments provided below will focus on claims 1, 3-6, 9 and 11, as amended.

Jones

Jones discloses a disposable applicator and method of using the applicator that is structurally and functionally different from the vaginal applicator and method of transvaginal drug delivery defined by the claims.

Jones is directed to delivering formulations for treating vaginal infections or contraception. (col. 1, lines 21-22) These formulations are administered so that they coat the vaginal cavity. Thus, a volume that is greater than 1 mL, typically about 4 to 5 mL, is

administered to a patient. Further, in use, a patient inserts the applicator into the opening of vaginal cavity, and does not insert the applicator until it reaches the upper vaginal vault. Thus, Jones is directed at delivering the formulation to the vagina, and is not directed at drug delivery through the vagina (*i.e.* transvaginal drug delivery), as required by the claims. Further, Jones is directed at delivering larger volumes of pharmaceutical formulations, and therefore is not suitable for delivering a precise amount of a small volume, *i.e.* 1 mL or less, to the upper vaginal vault.

As discussed, there are a number of structural differences between the claimed applicator and Jones' applicator. A few are highlighted below.

Jones' Applicator cannot be breech filled, as required by independent Claims 1 and 6

Jones contains four figures. Figures 1-3 illustrate the main embodiment, which has three parts, a separate container (17) designed to store the formulation, a disposable applicator (11) into which the prefilled container is placed for delivery of the formulation, and a plunger (10).

The widest open end (20) of the container (17) is filled with the pharmaceutical formulation and the formulation is stored in the container (col. 2, lines 57-60). This is not the same as breech filling. Breech filling, requires filling the applicator through the same opening through which the medicament is delivered to a patient (*see* Specification at page 5, lines 14-16).

Figure 4 of Jones illustrates a variation on the main embodiment. The device in illustrated in Figure 4 contains an applicator barrel (referred to as an "outer barrel") (11), a

plunger (referred to as an "inner barrel") (10) and a cap (referred to as a "moisture proof plug") (13). The applicator barrel has a constant inner diameter and does not contain a separate medication chamber within the applicator barrel, where the medication chamber defines a cavity having a volume of 1 mL or less.

Jones explains that the device in Figure 4 is filled by first sealing the end of the barrel through which the formulation will be administered to a patient with the cap (13), then partially filling the barrel (11) with the formulation (from the opposite, open end), and finally sealing the formerly open end with a "movable moisture-proof seal" (14) (*see* col. 2, lines 32-41). Thus, Jones does not disclose breech filling the device illustrated in Figure 4.

Jones' Applicator does not contain a medication chamber within the Applicator Barrel and is not able to deliver a precise, small volume of a Pharmaceutical Formulation

As noted above, neither of the applicator embodiments described in Jones contain a separate medication chamber within the applicator barrel. However, even if one could somehow construe Jones' applicator to contain a separate medication chamber, Jones' applicator is incapable of containing and delivering a precise small volume, *i.e.* 1 mL or less, of a pharmaceutical composition, as required by the claims.

For example, as shown in Figure 3 of Jones, the seal 21 cannot be pushed by the inner barrel (10) until the opening at the end of the applicator. Thus, some of the pharmaceutical formulation will remain the applicator even after the seal is pushed as far as it can go. In

contrast, claims 1 and 6, as amended, specify that (1) the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel and (2) the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier, which is located proximal to the opening at the proximal end of the applicator barrel. Thus, in the device defined by claim 1, the plunger can be pushed until the opening at the proximal end of the applicator barrel, which also corresponds with the opening of the medication chamber. This allows for all of the pharmaceutical formulation to be expelled from the applicator into the patient's body.

Claim 6, as amended, recites the step of "depressing the plunger until it reaches the barrier to administer all of the pharmaceutical formulation to the patient's upper vaginal vault". As noted above, the Jones device as illustrated in Figures 1-3 is designed so that it cannot deliver all of the pharmaceutical formulation that it contains. Further, as noted above, Jones is directed to delivering a relatively large volume (compared to the volume required by the claims) of a pharmaceutical composition within the vaginal cavity to coat the vaginal cavity. Thus Jones' applicator is not able to deliver all of the pharmaceutical formulation to a patient's upper vaginal vault, as required by claim 6 and its dependent claims.

The claimed Devices and Methods are not obvious in view of Jones

Jones' applicators are structurally and functionally different from the claimed applicator and are not suitable for the claimed method of transvaginal drug delivery. Jones describes delivery of pharmaceutical formulations "for the treatment of vaginal infections or for

contraception." (col. 1, lines 21-22) These formulations are administered in volumes greater than 1 ml, typically about 4 to 5 mL, so that they coat the vaginal cavity. Therefore it would not be obvious to one of ordinary skill in the art to modify Jones applicator because the necessary modifications would prevent Jones from achieving its purpose. Therefore claims 1, 3-6, 9, and 11, as amended, are novel and non-obvious over Jones.

Additionally, new claims 12 and 13 are non-obvious for at least the reasons discussed above with respect to independent claims 1 and 6. Jones' applicator has a blunt end which is generally not suitable for insertion into the vagina. In contrast, new claims 12 and 13 specify that the applicator contains a rounded tip. Therefore new claims 12 and 13 are non-obvious in view of Jones.

Allowance of claims 1, 3-6, 9, and 11-13, as amended, is respectfully solicited.

Respectfully submitted,

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